

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Yong D. Zhao

Examiner: Alter, Alyssa M.

Serial No. 10/668,789

Group Art: 3762

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Docket No.: P0010040.00

Title: MEDICAL ELECTRICAL LEAD SYSTEM INCLUDING PRE-FORMED
J-SHAPED STYLET

Appeal Brief

MAIL STOP Appeal Brief - Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following Appeal Brief is submitted pursuant to the Notice of Appeal mailed November 11, 2009. A one month extension of time is requested herewith.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

Request for Extension of Time

Under the provisions of 37 CFR §1.136(a), Applicant petitions to extend the period for filing a reply in the above-identified application as follows:

- 37 CFR § 1.17(a)(1)-Extension within first month.
- 37 CFR § 1.17(a)(2)-Extension within second month.
- 37 CFR § 1.17(a)(3)-Extension within third month.

Fees Associated with Extension

Payment of the fee for any requested extension is authorized in the above fee section.

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

None.

III. Status of the claims

Claims 1 - 30 are pending.

Claims 9 – 16 and 21 – 30 are presently withdrawn.

Claims 1 – 8 and 17 – 23 stand rejected under 35 U.S.C. 103 as obvious over Williams (U.S Patent No. 4,498,482).

Claims 1 – 4, 8 and 17 - 20 Stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013).

Claims 5 – 7 and 22 – 23 stand rejected as obvious over Dutcher in view of Hartley (US 20040073141 A1).

All rejections of Claims 1 – 8 and 17 - 23 are hereby appealed.

As claims withdrawn claims 9 – 16 and 21 – 30 depend upon claims 1 and 17 which are respectfully asserted to be allowable, allowance of these claims is also respectfully requested.

IV. Status of amendments

The Amendment mailed August 5, 2009 has been entered. No amendments were made to the claims at that time.

The Appendix of Claims reflects the claims as finally rejected.

V. Summary of claimed subject matter

The application has two independent claims on appeal, claims 1 and 17

1. Claim 1

Claim 1 sets forth a medical electrical lead system.

The system comprises a medical electrical lead including a proximal end, a distal portion, and an elongated lumen extending from the proximal end into the distal portion. the lead is illustrated in Figures 1 and 2. The proximal end is at 20. the distal end is at 40 and the lumen extending between them is formed within conductor coil 52, which may be rotated around the J-shaped stylet as discussed below. The lead is generally described in paragraph [0011].

The system also comprises a pre-formed j-shape stylet including a proximal end, a distal end, a substantially straight distal segment extending from the distal end, a curved intermediate segment extending from the substantially straight distal segment, a substantially straight proximal segment extending from the curved intermediate segment toward the proximal end, and a taper zone extending within the curved intermediate segment and having a gradual decrease in diameter. The straight distal segment extends from 31 to 38 in each figure. The straight distal segment is described in paragraphs [0016 – 18], with dimensions listed in paragraph 18. The curved intermediate segment extends from 31 to 35 in each figure. The curved intermediate segment is also described in paragraphs [0016 - 18]. The substantially straight proximal segment extends from 35 to 39 in each figure. The substantially straight proximal

segment is also described in paragraphs [0016 - 18]. In one embodiment, the taper zone extends from 38 to 33, and extends over the straight distal segment and within the distal portion of the curved intermediate segment. The taper zone is also described in Paragraphs [0016 - 18].

The system is configured such that the j-shape stylet is slideably received within the lumen of the lead such that the curved intermediate segment of the stylet imparts a similar curve to the distal portion of the lead. This aspect of the system is illustrated in Figure 1, which shows the stylet within the lumen of conductor 52 and illustrates the J-shape imparted to the lead. This aspect of the system is described in paragraph [0014].

2. Claim 17

Claim 17 sets forth a pre-formed J-shape stylet for use with a medical electrical lead.

The stylet comprises a substantially straight distal segment extending from a distal end. This segment is illustrated in Figures 3 and 4. The straight distal segment extends from 31 to 38 in each figure. The straight distal segment is described in paragraphs [0016 – 18], with dimensions listed in paragraph 18.

The stylet further comprises a curved intermediate segment extending from the substantially straight distal segment. This segment is illustrated in Figures 3 and 4. The curved intermediate segment extends from 31 to 35 in each figure. The curved intermediate segment is also described in paragraphs [0016 - 18].

The stylet further comprises a substantially straight proximal segment extending from the curved intermediate segment toward a proximal end. The substantially straight proximal segment extends from 35 to 39 in each figure. The substantially straight proximal segment is also described in paragraphs [0016 - 18].

The stylet further comprises a taper zone extending within the curved intermediate segment and having a gradual decrease in diameter. In one embodiment, the taper zone extends from 38 to 33, and extends over the straight distal segment and within the distal portion of the curved intermediate segment. The taper zone is also described in Paragraphs [0016 - 18].

VI. Grounds of rejection to be reviewed on appeal

1. Rejection over Williams

Claims 1 – 8 and 17 – 23 stand rejected under 35 U.S.C. 103 as obvious over Williams (U.S Patent No. 4,498,482).

Applicants respectfully traverse this rejection.

2. Rejection over Dutcher

Claims 1 – 4, 8 and 17 - 20 Stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013).

Applicants respectfully traverse this rejection.

3. Rejection over Dutcher and Hartley

Claims 5 – 7 and 22 – 23 stand rejected as obvious over Dutcher in view of Hartley (US 20040073141 A1).

Applicants respectfully traverse this rejection.

VII. Argument

1. Rejection over Williams

Claims 1 – 8 and 17 – 23 stand rejected under 35 U.S.C. 103 as obvious over Williams (U.S Patent No. 4,498,482).

Applicants respectfully traverse this rejection.

The rejection over Williams is expressly based upon the argument that it would be obvious to add a curve to the tapered portion of the Williams stylet in order to enhance the ability of the stylet to enhance maneuverability. This argument is contrary to the express teaching of the Williams patent, wherein the tapered portion is intended to allow the stylet to rotate smoothly within a J-shaped lead. Adding a preformed curve to such a stylet would frustrate the basic purpose of the stylet, which is to advance the fixation helix without causing the distal end of the lead to move about. Adding the Examiner's proposed J-shaped curve would cause the distal end of the lead to whip about as the stylet was rotated. Any pacing lead designer, or indeed any lay-person giving the matter a moment's thought, would recognize that this is so. Modifying the Williams stylet as proposed by the Examiner would make it unsuitable for its disclosed purpose and thus cannot be obvious.

Further, the teaching of the Dutcher patent discussed below is entirely consistent with this the teaching of Williams on this point. The pre-curved portion of the Dutcher stylet is not rotated during advancement of the fixation helix, precisely to avoid this problem. Thus, Dutcher also teaches against modifying the Williams stylet as suggested by the Examiner.

While the oft cited KSR decision allows the Examiner to use common sense in combining references, it also imposes the requirement that the Examiner actually demonstrate that the rejection conforms to common sense. The Examiner is referred to the recently published case of Perfect Web Technologies, Inc. v. Infousa, Inc., which explicitly sets forth this requirement.

The Examiner's proposed modification of the Williams stylet is contrary to the teaching of Williams, contrary to the teaching of Dutcher and contrary to common sense. Withdrawal of the rejections of claims 1 – 8 and 17 – 23 as obvious over Williams is therefore also respectfully requested.

2. Rejection over Dutcher

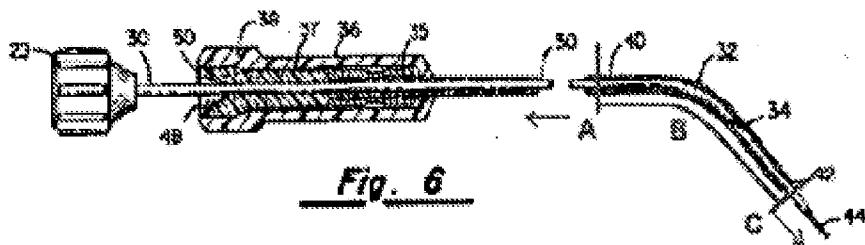
Claims 1 – 4, 8 and 17 - 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013).

Applicants respectfully traverse this rejection.

The claims require a stylet having a straight proximal segment, a curved intermediate segment extending from the proximal segment and a straight distal segment extending from the curved segment. All three segments are clearly visible in Dutcher. The straight proximal and distal segments are plainly visible in the inserted drawing. The area intermediate the straight segments is curved, as required by the claims.

The claims further require a taper zone displaying a decrease in diameter and extending within the intermediate, curved segment. It is indisputable that the taper in the Dutcher stylet is present only in a straight distal segment of the stylet, directly contrary to the requirements of the claims. The Examiner's arguments do not dispute this fact.

The Examiner characterizes Dutcher as having a taper zone extending within a "curved intermediate segment" based upon inclusion of the entire portion identified as B as the "curved segment" required by the claims.



However, as is plainly shown, the portion of B which includes the taper (reduction in diameter) is in fact straight and disclosed as deliberately so. In essence, the Examiner's argument is that if one calls the straight distal segment of Dutcher part of a "curved segment", the required taper of the present claims is now magically present in the "curved segment" of the claims. The labeling of the portions of the in Dutcher lead does not make the structure as illustrated anticipatory. The claims are not directed to a a taper extending into a "labeled stylet portion including a curved segment."

The examiner's response is that "the claim does not require that the taper is in a curved **portion** (emphasis added) of the curved segment." It is respectfully asserted that if a taper (reduction in diameter) located only along a straight part of a stylet can be interpreted as extending within a "curved segment" of a stylet, it correspondingly can be interpreted as extending along a "curved portion of a curved segment", if the "curved portion" is also interpreted as including the straight part. Rather than supporting the grounds for rejection, the Examiner's argument proves its inappropriateness.

It may be that the Examiner may be relying on some vagueness in the Dutcher patent with regard to the shape of the stylet. It is noted that to the extent the Dutcher disclosure is unclear it cannot be relied upon in an anticipation rejection. Anticipation requires more than simply not disclosing the contrary of the claimed invention.

The simple fact of the matter is that the taper (reduction of diameter) of the Dutcher stylet as disclosed extends only along a straight part of the stylet. The Examiner's interpretation of the claims is unreasonable based both upon normal English usage and in light of the disclosure of the present application, which clearly discloses embodiments in which tapers (reductions in diameter) extend along curved segments, portions, zones, parts or whatever else they may be called.

Withdrawal of the rejections of claims 1 – 4, 8 and 17 – 20 as anticipated by Dutcher is respectfully requested.

3. Rejection over Dutcher and Hartley

Claims 5 – 7 and 22 – 23 stand rejected as obvious over Dutcher in view of Hartley (US 20040073141 A1).

Applicants respectfully traverse this rejection.

As the rejections under Section 103 based in part on Dutcher rely on the underlying rationale for anticipation, these rejections are also believed unsupportable.

Withdrawal of the rejections of claims 5 – 7 and 22 – 23 as obvious over Dutcher in view of Hartley is therefore also respectfully requested.

With allowance of claims 1 and 17, the withdrawn claims dependent thereon should also be allowed. Allowance of withdrawn claims 9 – 16 and 24 – 30 is therefore also respectfully requested.

Respectfully submitted,

February 10, 2010
Date

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Appendix XIII - Claims

1. A medical electrical lead system, comprising

a medical electrical lead including a proximal end, a distal portion, and an elongated lumen extending from the proximal end into the distal portion; and

a pre-formed j-shape stylet including a proximal end, a distal end, a substantially straight distal segment extending from the distal end, a curved intermediate segment extending from the substantially straight distal segment, a substantially straight proximal segment extending from the curved intermediate segment toward the proximal end, and a taper zone extending within the curved intermediate segment and having a gradual decrease in diameter;

wherein the j-shape stylet is slideably received within the lumen of the lead such that the curved intermediate segment of the stylet imparts a similar curve to the distal portion of the lead.

2. The medical electrical lead system of claim 1, wherein the taper zone of the stylet extends from a first diameter within the substantially straight distal segment to a second diameter within the curved intermediate segment, the second diameter being greater than the first diameter.

3. The medical electrical lead system of claim 2, wherein the first diameter within the substantially straight distal segment coincides with the distal end of the stylet.

4. The medical electrical lead system of claim 1, wherein the taper zone of the stylet extends from a first diameter within the substantially straight proximal segment to a second diameter within the curved intermediate segment, the first diameter being greater than the second diameter.

5. The medical electrical lead system of claim 1, wherein the curved intermediate segment sweeps around approximately 210 degrees.

6. The medical electrical lead system of claim 1, wherein the curved intermediate segment sweeps around approximately 180 degrees.
7. The medical electrical lead system of claim 1, wherein the curved intermediate segment sweeps around between approximately 180 degrees and approximately 210 degrees.
8. The medical electrical lead system of claim 1, wherein the lead further includes an extendable / retractable helix terminating the distal portion of the lead.
9. (Withdrawn) The medical electrical lead system of claim 2, wherein the J-shape stylet further includes a second taper zone extending distally from a third diameter within the substantially straight proximal segment to a fourth diameter, the third diameter being greater than the fourth diameter and the fourth diameter being approximately equal to the second diameter.
10. (Withdrawn) The medical electrical lead system of claim 9, wherein the first diameter within the substantially straight distal segment coincides with the distal end of the stylet.
11. (Withdrawn) The medical electrical lead system of claim 9, wherein the fourth diameter resides within the substantially straight proximal segment.
12. (Withdrawn) The medical electrical lead system of claim 9, wherein the fourth diameter resides within the intermediate segment.
13. (Withdrawn) The medical electrical lead system of claim 9, wherein the curved intermediate segment sweeps around approximately 210 degrees
14. (Withdrawn) The medical electrical lead system of claim 9, wherein the curved intermediate segment sweeps around approximately 180 degrees.

15. (Withdrawn) The medical electrical lead system of claim 9, wherein the curved intermediate segment sweeps around between approximately 180 degrees and approximately 210 degrees.

16. (Withdrawn) The medical electrical lead system of claim 9, wherein the lead further includes an extendable / retractable helix terminating the distal portion of the lead.

17. A pre-formed J-shape stylet for use with a medical electrical lead, comprising:

- a substantially straight distal segment extending from a distal end;
- a curved intermediate segment extending from the substantially straight distal segment;
- a substantially straight proximal segment extending from the curved intermediate segment toward a proximal end; and
- a taper zone extending within the curved intermediate segment and having a gradual decrease in diameter.

18. The stylet of claim 17, wherein the taper zone extends from a first diameter within the substantially straight distal segment to a second diameter within the curved intermediate segment, the second diameter being greater than the first diameter.

19. The stylet of claim 18, wherein the first diameter within the substantially straight distal segment coincides with the distal end of the stylet.

20. The stylet of claim 17, wherein the taper zone extends from a first diameter within the substantially straight proximal segment to a second diameter within the curved intermediate segment, the first diameter being greater than the second diameter.

21. (Original) The stylet of claim 17, wherein the curved intermediate segment sweeps around approximately 210 degrees.

22. The stylet of claim 17, wherein the curved intermediate segment sweeps around approximately 180 degrees.
23. The stylet of claim 17, wherein the curved intermediate segment sweeps around between approximately 180 degrees and approximately 210 degrees.
24. (Withdrawn) The stylet of claim 18, further comprising a second taper zone extending distally from a third diameter within the substantially straight proximal segment to a fourth diameter, the third diameter being greater than the fourth diameter and the fourth diameter being approximately equal to the second diameter.
25. (Withdrawn) The stylet of claim 24, wherein the first diameter within the substantially straight distal segment coincides with the distal end of the stylet.
26. (Withdrawn) The stylet claim 24, wherein the fourth diameter resides within the substantially straight proximal segment.
27. (Withdrawn) The stylet of claim 24, wherein the fourth diameter resides within the intermediate segment.
28. (Withdrawn) The stylet of claim 24, wherein the curved intermediate segment sweeps around approximately 210 degrees
29. (Withdrawn) The stylet of claim 24, wherein the curved intermediate segment sweeps around approximately 180 degrees.
30. (Withdrawn) The stylet of claim 24, wherein the curved intermediate segment sweeps around between approximately 180 degrees and approximately 210 degrees.

IX. Appendix – Evidence

None

X. Appendix – Other proceedings

None